K081264

Children's Health First, Inc.

PO Box 4056 Carlsbad, CA 92018

5. "510 (k) Summary " Rev. K081264

FEB 13 2009

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Contact: Roger T. Vaughan

Submission preparation date: April 28, 2008 / December 20th, 2008/February 12,2009

Device Trade name: STATStrap ™ Neonatal Incubator Safety Strap
Common name: Neonatal Incubator restraint strap
Classification name: Neonatal Transport Incubator (accessory);(21CFR880.5410), Product code: FPL)

Substantial Equivalence:

K031096/K850496A	Model 185 with restraint straps 880.5410 Part #216-0350 Restraint Straps	International Bio Medical Airborne Life Support
K001019/K941106	Model TI500 & Ti500 with restraint straps / 880.5410 Part # MU06011	Hill-ROM Airshield Draeger Medical Inc.

Device Description:

The STATStrap™ Neonatal Incubator Safety Strap is a soft closed cell foam material covered with a laminate of soft fabric that allows Hook (Velcro® style) fabric to attach to it along the straps entire length. The end of each strap incorporates a hook fabric wing tab or a wire spring hook, so as to attach each strap to the infant incubator tray. These 13 inch straps are positioned in four positions along the infant incubator mattress tray so as to fit the patient's size. Once the straps are in place and securely fastened to the mattress tray, the straps cross over the neonate (infant's) body in a "X" pattern and attach to each other so as to provide positioning aid, prevent gross body movement or falls of the patient. A hook "tie strap" is included on both models to secure the two main straps together into a single unit. These straps are single patient use disposable items. Labeling states the disposable nature of the strap, precautions and the use instructions.

Intended Use:

The intended use of this (single patient use) safety strap set is to act as a positioning aid and to prevent accidental falls of the pre-term (< 38 weeks gestational age) and term newborn (≥ 38 weeks gestational age) from the transport incubator while within a medical facility. This strap(s) is not intended as a vehicular restraint device and will provide minimal protection in the event of a vehicle / aircraft crash or rapid deceleration. This device should be viewed by the user as a positioning aid and safety restraint of the infant's torso, hips and legs while occupying neonatal transport incubator(s). Infants requiring use of a transport incubator should be secured in the transport incubator as the manufacture has designed in order to mitigate falls and internal impact within the incubator chamber. Like the safety straps provided with transport incubators, these straps function in the same manner to prevent falls and trauma of the newborn and to assist in positioning the newborn for needed medical interventions and therapies.

The major difference between the safety straps provided by incubator manufactures and the STATStrap™ Neonatal Incubator Safety Strap models is that the latter device is labeled for single patient use, as well as with use and care instructions. We feel that this adds to the safe and effectiveness of the device(s).

STATStrap™ Neonatal Incubator Safety Strap #SS-001 is designed with winged Hook fabric tabs to connect to the transport incubator mattress tray for incubators manufactured with horizontal connection slits.

STATStrap™ Neonatal Incubator Safety Strap #SS-002 is designed with stainless steel metal spring hooks so as to connect to transport incubator mattress tray for incubators manufactured with circular mounting holes,

Both #SS-001 and #SS-002 use hook fabric tabs to facilitate the opposing straps to fasten to each other along the strap's length.

Both #SS-001 and #SS-002 incorporate a final safety "tie strap" which joins the two main straps inorder to keep the main straps in the position that they were placed by the user. Its' application also helps in ensuring that the main straps are not positioned too tightly on the patient's chest, or have the potential to separate from each other and pose a strangulation hazard.

Summary of Characteristics to predicate devices: Table format

	Foam base with fabric laminate	Device Labeled with name and company	Device currently used as a pediatric restraint in a Neonatal Transport Incubator	Attachment mechanism Hook & Loop /Foam	Intended purpose to restrain neonate against falls / trauma
STATStrap™ SS-001 & SS-002 K081264	yes	yes	Pending 510K /SE	yes	yes
IB Inc. Airborne LS					

K031096/K850496A	yes	no	yes	yes	yes
Hill-ROM Airshield Draeger Medical Inc. K001019/K941106	yes	no	yes	yes	yes

	Device labeled as "Single Patient Use"	Device Section listed	Product Code assigned
STATStrap™ SS-001 & SS-002 K081264	yes	Request 880.5410	Request FPL
IB Inc. Airborne LS K031096/K850496A	no	880.5410	FPL
Hill-ROM Airshield Draeger Medical Inc. K001019/K941106	no	880.5410	FPL

As the tables demonstrates, the use of the predicate serve the same function.
The STATStrap™ Neonatal Incubator Safety Strap serves the same purpose as the predicate product compared. All of these devices use the same design, material, chemical composition, and physical energy source to work. The only difference may be in material length of devices, packaging, labeling, and attachment mechanism to the bed tray.

Clinical Data: Not applicable

Summary / Conclusion from Testing: Not applicable

End of 510K Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Children's Health First, Incorporated
Mr. Roger T. Vaughan
Vice President Sales & Marketing
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FEB 13 2009

Re: K081264
Trade/Device Name: STATStrap™ Neonatal Transport Incubator Safety Strap
Regulation Number: 21 CFR 880.5410
Regulation Name: Neonatal Transport Incubator
Regulatory Class: II
Product Code: FPL
Dated: January 27, 2009
Received: February 10, 2009

Dear Mr. Vaughan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for
Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K081264

Device Name: STATStrap™ Neonatal Transport Incubator Safety Strap

Indications For Use: Securing newborn infants of various sizes and weights within a Neonatal Transport Incubator.

Patient population: Newborn infants / Gestation age of 24 weeks- 40 weeks

Condition of use/ Normal Use of device: Inner hospital transports only, not intended as a motor vehicle restraint device. Used to position newborn infant, and help to prevent falls from, and gross movement within, transport incubators.

Rx Only

"Caution: Federal law restricts this device to sale by or on the order of a licensed physician"

Pescription Use ___x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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